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III. Examiner Interview Summary

In a telephone conversation of January 26, 2004 between Examiner Sisson and Gloria L. Norberg, Examiner Sisson clarified the Advisory Action rejection as applying to all claims, not just the claims to a single stranded embodiment. The receptor length of 1mm was believed by the Examiner to apply to the particle and the receptor together, and was believed too long for describing the length of the receptor. The Examiner stated a preference for claim language to a specific number of nucleobases as the receptor length, or acceptable functional language as to the receptor length.

Applicants' representative appreciates the courtesy of the examiner in returning her telephone call and clarifying the rejection.

IV. Remarks

A. Status of the Application

Claims 35-37 are amended. Claims 8-11 and 35-37 are pending.

B. Rejections of Claims 8-11 and 35-37 under 35 U.S.C. §112, First Paragraph Office Action

Claims 8-11 and 35-37 were rejected in the Final Office Action for introduction of new matter. In particular, Claims 35-37 were rejected for the following: "where target receptors have a length of up to 1mm," "a labeled complex having a predetermined molar ratio of the labeled substances," and "number and length of target receptors."

Claim 35 was rejected in the Final Office Action for "where single-stranded target receptors have a predetermined base sequence."

The Advisory Action states that the response filed December 29, 2003 does not place the application in condition for allowance because: a review of page 9 and of original claim 3 fails to find support for where the "target receptors," which "are single-stranded nucleic acids of a predetermined base sequence are "of length up to 1mm." Support is cited as present for where the combination of "target receptor, which is bonded with the carrier on a part thereof, and bonded with the labeled substance on the other part thereof, is formed in a slender shape" which can be of a length of up to 1mm. The combination of elements was cited as not teaching that the "target receptor" alone, which must be of a predetermined sequence and be single stranded nucleic acid, be of that length.

Response

The phrase "of length up to 1mm" has been removed from the independent claims. Functional language describing the length of the receptor is present in Claims 35-37 in the "wherein" clause and has support as set forth below.

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Support for the remaining objectionable claim language of the independent claims is found in the specification and originally filed claims as follows:

In the third aspect of the invention (begins on page 8, last line), the target receptor is formed in a slender shape (page 9, line 1-3). Further, the target receptor is alone referred to as being in a slender shape since the rest of the sentence is set off in phrases with commas. Therefore, the "slender shape" refers to the receptor only.

In the fifth aspect of the invention (begins on page 10, line 18), which refers to any one of the first through the fourth aspects of the invention, the target receptor has a predetermined double strand base sequence. Therefore, this aspect refers to the third aspect which describes the target receptor in a slender shape. Therefore, the receptor may be a double strand base sequence of predetermined sequence in a slender shape.

In the seventh aspect of the invention (begins on page 11, line 11), which refers to any one of the first through the fifth aspects of the invention, the target receptor is a single strand nucleic acid. Therefore, this aspect refers to the fifth aspect which describes the receptor as double stranded, and the seventh aspect further describes the target receptor as denatured to a single strand. This aspect still has a predetermined base sequence and a slender shape.

Therefore, the seventh aspect of the invention describes a target receptor as having a slender shape, as being a single strand nucleic acid, and having a predetermined base sequence.

With regard to the length of a "slender shape," at page 9 and in Claim 3 as originally filed, the target receptor is cited as formed in a slender shape (page 9, line 3). The size of the "slender shape" is not expressly defined (page 9, line 5), however, for example, the form is as long as or sufficiently longer than the particle size (page 9, lines 7-8), for example, about 10 times as long as the particle size, for example, about 10 μ m (page 9, lines 8-9).

At page 5, the particle size is cited as preferably of the order of about 0.1 μ m ~ about 1 mm (lines 11-13). Therefore, the target receptor may be from 0.1 μ m to about 10 mm. The Office Action of Feb. 12, 2003 requested that a limit be put on the length of immobilized polynucleotides. Since the value of 1 mm is expressly stated in the specification, that value was selected as a limit on the length of target receptors.

The Advisory Action repeated the rejection of the phrase "of length up to 1mm" as a limitation not found in the original disclosure and, in an Examiner's Interview, Examiner Sisson clarified that the rejection applied to all claims.

The receptor, in a slender shape, functions as a spacer (page 9, lines 10-11). As supported by page 9, lines 10-23, the "slender shape" and, therefore, the length of the receptor is such that a major influence by energy movement or quenching among the labeled substances does not occur, thereby

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enhancing discrimination by stable emission, as stated in independent Claims 35-37. Lines 10-23 of page 9 are repeated here:

The reason why a slender shape is formed is to make it play a role as a spacer where, by attaching a labeled substance such as a luminescent material and the like on one end, compared with the case of attaching the labeled substance to a carrier such as a micro particle and the like, the space to the carrier and the space and distance between the labeled substances are expanded, and hence energy movement between the labeled substances and the occurrence of quenching are prevented, so that it guarantees more reliably the possibility of consistent discrimination of emissions and the like. According to the present invention, since a larger space can be obtained between the labeled substances compared with direct bonding to the carrier, interactions such as energy movement between the labeled substances, quenching (in the case of luminescent material), and the like are prevented, so that for example a number of substances, more than thousands and tens of thousands, can be discriminated consistently and with high accuracy.

Applicants believe that support for the claim language "length of the receptor is such that a major influence by energy movement or quenching among the labeled substances does not occur, thereby enhancing discrimination by stable emission" of Claims 35-37 is present as set forth above and that the cited phrase of said claims functionally defines the length of the receptor. One of ordinary skill in the art, in light of the present disclosure, would be able to determine without undue experimentation the length of a receptor "such that a major influence by energy movement or quenching among the labeled substances does not occur, thereby enhancing discrimination by stable emission."

Since the independent claims are supported by the specification as filed, claims dependent thereon also have support. Applicants respectfully request that the rejection of Claims 8-11 and 35-37 under 35 U.S.C. §112, first paragraph, be withdrawn for the reasons cited herein.

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C. Conclusion

It is believed that all matters set forth in the Final Office Action and Advisory Action have been addressed. Entry of the Response to Final Office and this Supplemental Response is respectfully requested. Further reconsideration and an early indication of the allowability of the pending claims are respectfully requested. Should the Examiner believe that an interview with Applicant's undersigned agent would expedite consideration of the pending claims, the Examiner is invited to call the undersigned agent at 512.867.8528.

Respectfully submitted,

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